

## CLAIMS

1. A composition containing an extremely poorly water-soluble drug, obtained by treating, with a supercritical fluid or subcritical fluid of carbon dioxide, a mixture comprising a porous silica material and said extremely poorly water-soluble drug, wherein said porous silica material has an average pore diameter in a range of from 1 to 20 nm, pores having diameters within  $\pm 40\%$  of said average pore size account for at least 60% of a total pore volume of said porous silica material, and in X-ray diffractometry, said porous silica material has at least one peak at a position of diffraction angle ( $2\theta$ ) corresponding to a d value of at least 1 nm.

2. The composition according to claim 1, wherein said porous silica material has an average pore diameter of from 1 to 20 nm.

3. The composition according to claim 1, wherein said porous silica material has an average pore diameter of from 1.5 to 10 nm.

4. The composition according to claim 1, wherein said porous silica material has an average pore diameter of from 2 to 3 nm.

5. The composition according to any one of claims 1-4, wherein said porous silica material has a specific surface area of from 100 to 2,000  $\text{m}^2/\text{g}$ .

6. The composition according to any one of claims 1-4,

wherein said porous silica material has a specific surface area of from 600 to 1,800 m<sup>2</sup>/g.

7. The composition according to any one of claims 1-4, wherein said porous silica material has a specific surface  
5 area of from 800 to 1,500 m<sup>2</sup>/g.

8. The composition according to any one of claims 1-7, wherein a mixing ratio of said porous silica material to said an extremely poorly water-soluble drug is from 0.1:1 to 1,000:1.

10 9. The composition according to any one of claims 1-8, wherein said an extremely poorly water-soluble drug is 2-benzyl-5-(4-chlorophenyl)-6-[4-(methylthio)phenyl]-2H-pyridazin-3-one.

10. A medicinal preparation comprising a composition  
15 with an extremely poorly water-soluble drug contained therein as defined in any one of claims 1-9.

11. A process for producing a composition with an extremely poorly water-soluble drug contained therein as defined in any one of claims 1-9, which comprises placing a  
20 porous silica material and said extremely poorly water-soluble drug in a pressure vessel, filling said pressure vessel with carbon dioxide, treating said porous silica material and said extremely poorly water-soluble drug while controlling a temperature and pressure within said vessel such that carbon  
25 dioxide is maintained in a supercritical state or subcritical

state, and then discharging carbon dioxide to recover the resulting composition, wherein said porous silica material has an average pore diameter in a range of from 1 to 20 nm, pores having diameters within  $\pm 40\%$  of said average pore size account for at least 60% of a total pore volume of said porous silica material, and in X-ray diffractometry, said porous silica material has at least one peak at a position of diffraction angle ( $2\theta$ ) corresponding to a d value of at least 1 nm.

10           12. The process according to claim 11, wherein a weight ratio of said extremely poorly water-soluble drug to a supercritical fluid or subcritical fluid of carbon dioxide is from 1:1 to 1:1,000,000.

15           13. The process according to claim 11 or 12, wherein a temperature of treatment with a supercritical fluid or subcritical fluid is from  $-40$  to  $100^{\circ}\text{C}$ .

14. The process according to any one of claims 11-13, wherein a pressure of treatment with a supercritical fluid or subcritical fluid is from 1 to 50 MPa.

20           15. The process according to any one of claims 11-14, wherein a time of treatment with a supercritical fluid or subcritical fluid is from 1 minute to 24 hours.

25           16. A process for producing a composition with an extremely poorly water-soluble drug contained therein as defined in any one of claims 1-9, which comprises placing a

porous silica material and said extremely poorly water-soluble drug in a pressure vessel, controlling a temperature within said vessel such that carbon dioxide will be maintained in a supercritical state or subcritical state, filling said pressure vessel with carbon dioxide at such a pressure that carbon dioxide is maintained in said supercritical state or subcritical state, maintaining said supercritical state or subcritical state to treat said porous silica material and said extremely poorly water-soluble drug, and then discharging carbon dioxide to recover the resulting composition, wherein said porous silica material has an average pore diameter in a range of from 1 to 20 nm, pores having diameters within  $\pm 40\%$  of said average pore size account for at least 60% of a total pore volume of said porous silica material, and in X-ray diffractometry, said porous silica material has at least one peak at a position of diffraction angle ( $2\theta$ ) corresponding to a d value of at least 1 nm.

17. The process according to claim 16, wherein a weight ratio of said extremely poorly water-soluble drug to a supercritical fluid or subcritical fluid of carbon dioxide is from 1:1 to 1:1,000,000.

18. The process according to claim 16 or 17, wherein a temperature of treatment with a supercritical fluid or subcritical fluid is from  $-40$  to  $100^{\circ}\text{C}$ .

19. The process according to any one of claims 16-18,

wherein a pressure of treatment with a supercritical fluid or subcritical fluid is from 1 to 50 MPa.

20. The process according to any one of claims 16-19, wherein a time of treatment with a supercritical fluid or  
5 subcritical fluid is from 1 minute to 24 hours.